Provisional vs complex stenting strategy for coronary bifurcation lesions: meta-analysis of randomized trials

CRD summary
This review found that provisional stenting, as an initial strategy, was superior to complex stenting and it was associated with a lower risk of myocardial infarction. The review was generally well conducted, but the absence of the full quality assessment results means that the authors’ conclusions should be interpreted with caution.

Authors’ objectives
To determine the best method of percutaneous coronary intervention for coronary bifurcation lesions by comparing clinical and angiographic outcomes of provisional versus complex stenting strategies.

Searching
PubMed, EMBASE, Cochrane Central Register of Controlled Trials (CENTRAL), and ClinicalTrials.gov were searched for relevant studies from January 1998 to September 2008; search terms were reported. Google Scholar was also used to search the Internet. The reference lists of identified articles and reviews were searched for additional studies. The authors also searched published abstracts from several meetings and handsearched several relevant journals. There were no language restrictions.

Study selection
Randomised controlled trials (RCTs) with more than 30 patients in each group and at least six months of follow-up were eligible for inclusion if provisional stenting was compared with complex stenting, in patients with coronary bifurcation lesions. Additional inclusion criteria were that the trials had to report the outcomes of target lesion revascularisation, angiographic restenosis of the main vessel and side branch, stent thrombosis, myocardial infarction, death, and major adverse cardiac events.

Most of the included trials used sirolimus-eluting stents, while paclitaxel-eluting stents were used in one study. The primary outcome of interest was the incidence of major adverse cardiac events. The mean age of the patients ranged from 58 to 67 years and nearly 80% of them were male. Significant co-morbidities included diabetes mellitus (20% of included patients) and hypertension (58%). Patients’ left ventricular ejection fraction ranged from 55 to 61%. The complex stenting techniques varied across the trials and included crush, culotte, and t-stenting.

Two reviewers independently selected the trials and disagreements were resolved by consensus.

Assessment of study quality
Methodological quality was evaluated using Cochrane criteria, which included aspects of randomisation, assessor blinding, and performance of the analysis according to intention-to-treat principles. The authors did not state how many reviewers assessed trial quality.

Data extraction
Two reviewers independently extracted data to calculate risk ratios and 95% confidence intervals for the clinical and angiographic outcomes. Categorical measures were presented as percentages, and continuous variables were presented as means with corresponding standard deviations. Any disagreements were resolved by consensus.

Methods of synthesis
Pooled risk ratios and 95% confidence intervals were calculated using the DerSimonian and Laird random-effects model. Statistical heterogeneity across trials was evaluated, using the Cochran Q, Mantel-Haenszel, and the I² tests. The authors assessed publication bias, using the adjusted rank correlation test and by a visual appraisal of funnel plots.

Results of the review
Six RCTs (n=1,641 patients) were included. Follow-up ranged from six to 24 months, with a mean clinical duration of 10.34 months. Angiographic follow-up varied from six to nine months after the index procedure. Five of the six trials performed intention-to-treat analyses; the remaining trial performed end-point analysis by actual treatment. All six trials were included in the meta-analyses.

Complex stenting strategies were associated with a statistically significantly higher incidence of myocardial infarction (6.8%) compared with provisional stenting strategies (3.6%; RR 1.71, 95% CI 1.02 to 2.88). This was largely driven by one large trial (n=500).

For the primary outcome of major adverse cardiac events, there was a higher incidence in the complex stenting group (12.6%) compared with provisional stenting (9.6%), but there was no statistically significant difference between the groups (RR 1.23, 95% CI 0.91 to 1.68).

There were no statistically significant differences between provisional and complex stenting strategies for the incidence of mortality, target lesion revascularisation, stent thrombosis, main vessel restenosis, nor side-branch restenosis.

No statistically significant heterogeneity was found across the trials for any of the outcomes evaluated and a visual inspection of the funnel plots indicated that the risk of publication bias was low. Crossovers were between 2 and 18% in five trials, while in one trial 50% of patients who were assigned to the provisional stenting arm eventually received complex stenting.

**Authors' conclusions**
Provisional stenting as an initial strategy was superior to complex stenting for coronary bifurcation lesions and it was associated with a lower risk of myocardial infarction.

**CRD commentary**
This review addressed a clear question and the criteria for the inclusion of trials were clearly stated. Appropriate electronic databases were searched and attempts were made to identify unpublished trials. There was no evidence of publication bias and no language restrictions were applied. Steps were taken to minimise error and bias in the selection of trials and the extraction of data, but they were not reported for the assessment of quality. The reviewers did not fully report the results of the quality assessment. The pooling of results appears to have been justified, given the low levels of statistical heterogeneity observed between trials.

The review was generally well conducted, but the absence of the full quality assessment results means that the findings and the authors' conclusions should be interpreted with caution.

**Implications of the review for practice and research**
**Practice**: The authors stated that routine stenting of the side branch as part of a complex stenting strategy was not warranted and might have undesired clinical outcomes, including an increased rate of myocardial infarction. Complex stenting strategies should not be used routinely and should be reserved for particular cases where severe stenosis is present and involving the ostium of a large side branch.

**Research**: The authors stated that randomised evaluation of fractional flow reserve-based approaches to guide interventions to the side branch was needed.

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